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IAP20 Rec'd PCT/PTO 31 JAN 2006

Docket No.: 4705-0117PUS1
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ogari PACHECO et al.

Application No.: NEW

Confirmation No.: N/A

Filed: January 31, 2006

Art Unit: N/A

For: STABLE PHARMACEUTICAL
COMPOSITION OF FLUOROETHER
COMPOUND FOR ANESTHETIC USE,
METHOD FOR STABILIZING A
FLUOROETHER COMPOUND, USE OF
STABILIZER AGENT FOR PRECLUDING
THE DEGRADATION OF A FLUOROETHER
COMPOUND

Examiner: Not Yet Assigned

LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The PTO is requested to use the amended sheets/claims attached hereto (which correspond to the International Preliminary Examination Report (Article 34)) during prosecution of the above-identified national phase PCT application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37.C.F.R. §1.16 or 1.14; particularly, extension of time fees.

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Dated: January 31, 2006

Respectfully submitted,

By Mark J. Nuell

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Attachment(s)

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AMENDED CLAIMS

We claim:

1. Stable pharmaceutical composition, characterized by comprising an amount of a fluoroether anesthetic compound selected from the group constituted of sevoflurane, desflurane, isoflurane, enflurane and methoxyflurane, and at least one stabilizer agent employed in a concentration ranging from 0.001% to 5% in weight of the final composition, being the stabilizer agent a polyalcohol selected from the group constituted of propylene glycol, polyethylene glycol, hexylene glycol, 1,3-butyleneglycol, or a C₁-C₆ alkyl substituted or unsubstituted aliphatic 4-12 membered carbocyclic alcohol like menthol, or mixtures thereof.
- 15 2. Stable anesthetic pharmaceutical composition characterized by comprising an amount of sevoflurane and at least one stabilizer agent, employed in a concentration ranging from 0.001% to 5% in weight of the final composition, being the stabilizer agent a polyalcohol selected from the group constituted of propylene glycol, polyethylene glycol, hexylene glycol, 1,3-butyleneglycol, or a C₁-C₆ alkyl substituted or unsubstituted aliphatic 4-12 membered carbocyclic alcohol like menthol, or mixtures thereof.
- 20 25 3. Stable anesthetic pharmaceutical composition according to claim 2 wherein the stabilizing agent is propylene glycol employed in a concentration ranging from 0.001% to 0.200% in weight of the final composition.
- 30 4. Stable anesthetic pharmaceutical composition according to claim 2 wherein the stabilizer agent is a polyethylene glycol of general formula H(OCH₂CH₂)_nOH where n is equal or greater than 4 employed in a concentration ranging from 0.001% to 0.200% in weight of the final composition.

5. Stable anesthetic pharmaceutical composition according to claim 4 wherein the stabilizer agent is polyethylene glycol 400.
6. Stable anesthetic pharmaceutical composition according
5 to claim 2 wherein the stabilizing agent is menthol.
7. Stable anesthetic pharmaceutical composition according to claim 6 wherein menthol is used in a concentration ranging from 0.001% to 0.200% in weight of the final composition.
10. 8. Stable anesthetic pharmaceutical composition characterized by comprising an amount of sevoflurane and propylene glycol in a concentration ranging from 0.005% to 0.100% in weight of the final composition.
15. 9. Stable anesthetic pharmaceutical composition characterized by comprising an amount of sevoflurane and polyethylene glycol 400 in a concentration ranging from 0.005% to 0.100% in weight of the final composition.
20. 10. Stable anesthetic pharmaceutical composition characterized by comprising an amount of sevoflurane and menthol in a concentration ranging from 0.005% to 0.100% in weight of the final composition.
25. 11. Method for stabilizing sevoflurane characterized by using at least one stabilizer agent in a concentration ranging from 0.001% to 5% in weight in relation to the weight of sevoflurane, being the stabilizer agent a polyalcohol selected from the group constituted of propylene glycol, polyethylene glycol, hexyleneglycol, 1,3-butyleneglycol, or a C₁-C₆ alkyl substituted or
30 unsubstituted aliphatic 4-12 membered carbocyclic alcohol like menthol, or mixtures thereof.
12. Method according to claim 11 wherein the stabilizer agent is propylene glycol employed in a concentration

ranging from 0.001% to 0.200% in weight in relation to the weight of sevoflurane.

13. Method according to claim 11 wherein the stabilizer agent is a polyethylene glycol of general formula H(OCH₂CH₂)_nOH where n is equal or greater than 4 employed in a concentration ranging from 0.001% to 0.200% in weight in relation to the weight of sevoflurane.
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14. Method according to claim 13 wherein the stabilizer agent is polyethylene glycol 400.
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15. Method according to claim 11 wherein the stabilizer agent is menthol employed in a concentration ranging from 0.001% to 0.200% in weight in relation to the weight of sevoflurane.
16. Method for stabilizing anhydrous fluoroether compounds characterized by using at least one stabilizer agent employed in a concentration ranging from 0.001% to 5% in weight in relation to the weight of the fluoroether compound, being the stabilizer agent a polyalcohol selected from the group constituted of propylene glycol, polyethylene glycol, hexylene glycol, 1,3-butylene glycol, or a C₁-C₆ alkyl substituted or unsubstituted aliphatic 4-12 membered carbocyclic alcohol like menthol.
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17. Method according to claim 16 wherein the stabilizer agent is propylene glycol.
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18. Method according to claim 17 wherein propylene glycol is used in a concentration ranging from 0.001% to 0.200% in weight in relation to the fluoroether compound.
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19. Method according to claim 16 wherein the stabilizer agent is a polyethylene glycol of general formula H(OCH₂CH₂)_nOH where n is equal or greater than 4.

20. Method according to claim 19 wherein the stabilizer agent is polyethylene glycol 400.
21. Method according to claim 20 wherein polyethylene glycol 400 is used in a concentration ranging from 5 0.001% to 0.200% in weight in relation to the fluoroether compound.
22. Method according to claim 16 wherein menthol is used in a concentration ranging from 0.001% to 0.200% in weight in relation to the fluoroether compound.
- 10 23. Method according to claim 16 wherein the anhydrous fluoroether compound is sevoflurane.
24. Method for stabilizing a fluoroether compound presenting water content from 0.002% to 0.14% characterized by using at least one stabilizer agent employed in a concentration ranging from 0.001% to 5% 15 in weight in relation to the fluoroether compound being the stabilizer a polyalcohol selected from the group constituted of propylene glycol, polyethylene glycol, hexylene glycol, 1,3-butylene glycol, or a C₁-C₆ alkyl substituted or unsubstituted aliphatic 4-12 membered carbocyclic alcohol like menthol.
- 20 25. Method according to claim 24 wherein the stabilizer agent is propylene glycol.
26. Method according to claim 25 wherein propylene glycol 25 is used in a concentration ranging from 0.001% to 0.200% in weight in relation to the fluoroether compound.
27. Method according to claim 24 wherein the stabilizer agent is a polyethylene glycol of general formula 30 H(OCH₂CH₂)_nOH where n is equal or greater than 4.
28. Method according to claim 27 wherein the stabilizer agent is polyethylene glycol 400.

29. Method according to claim 28 wherein polyethylene glycol 400 is used in a concentration ranging from 0.001% to 0.200% in weight in relation to the fluoroether compound.

5 30. Method according to claim 24 wherein menthol is used in a concentration ranging from 0.001% to 0.200% in weight in relation to the fluoroether compound.

31. Method according to claim 24 wherein the fluoroether compound presenting water content ranging from 0.002% to 0.14% is sevoflurane.

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